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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/553,389	04/11/2006	Ragnar Ek	1501-1352-1	9006

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EXAMINER	
CHANNAVAJJALA, LAKSHMI SARADA	
ART UNIT	PAPER NUMBER
1611	

NOTIFICATION DATE	DELIVERY MODE
03/09/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DocketingDept@young-thompson.com

Office Action Summary	Application No.	Applicant(s)	
	10/553,389	EK, RAGNAR	
	Examiner	Art Unit	
	Lakshmi S. Channavajjala	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 December 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt of amendment and response dated 12-4-09 is acknowledged.

Claims 1-32 are pending.

The following rejection of record has been maintained:

Claim Rejections - 35 USC § 102

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 1-5, 8-12, 16, 22 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by US 4,450,151 ('151).

'151 teach an aerosol composition obtained by first preparing a suspension of hydrophobic powdered substance, alcohol and water; and further adding an intentional medicine. The composition of '151 is used for spraying on the skin and adheres to the skin (abstract). In order to prevent the clogging of agglomerates of water, alcohol and powder substance, '151 teaches addition of a gas propellant, which can be LPG or dimethyl ether, described in the examples of col. 5-10 (reads on instant claim 2). Examples also teach 30% water, alcohols, polymer such as starch and thus read on claim 3-5. The limitation "excipient particles after actuation can form a matrix, in- situ, on the administration site, such as the skin" in claim 8 is a future intended use and hence not given patentable weight. Besides, the composition of '151 includes the claimed features and hence is capable of forming a matrix in- situ, on the administration site, such as the skin. '151 teaches medicines such as cortisone, methylsalicylate etc., which are either soluble or suspended in the composition. The burden is on applicants to show

that the compounds do not meet any of the claimed states i.e., dissolved, partially dissolved or suspended". While '151 do not teach formation of larger aggregates explicitly, the very reason to include gas propellant is to prevent clogging by aggregates. Thus, it is implicit that the powder particles of '151 form large aggregates as in claim 12. In col. 1, L 64-67, '151 teaches particles sizes of 70 to 325 mesh, where 70 mesh is about 200-500 microns and thus is within the size range of instant claim 11. With respect to claim 16, it is the position of the examiner that the particles of '151 meet the claimed features because the spray composition has powder particles that do not fly and adhere to skin uniformly. The burden is on applicants to show that particles of '151 do not have isodiametrical shape and smooth texture. For claim 22, '151 teach a skin spray. For claim 25, '151 teach cortisone that is capable of treating allergies on skin and hence treats disorders claimed. Thus, '151 anticipate instant claims.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 15, 21, 24 and 26-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,450,151 ('151).

'151 do not teach the particle sizes of claim 15and the specific limitations of applying the spray according claims 21, 24 and 26-32. However, '151 teaches a range of particle sizes for easy application, good adhesion and excellent feeling upon skin

adhesion and therefore, it would have been obvious for a skilled artisan at the time of the instant invention was made to employ optimum size of particles of the solid powder in '151 such that the ability of the composition to adhere to skin and thus impart the benefits desired are not compromised. Further, a skilled artisan would have readily been able to choose the appropriate ways of spraying the composition of '151 i.e., the height of application, area on the skin, opening of the spray pump, time of application, such that the medicament being administered is effectively administered. Additionally, instant claims do not recite any specific height, area on skin, opening diameter of the pump etc.

1. Claims 17-18 rejected under 35 U.S.C. 103(a) as being unpatentable over US 4450151 as applied to claims 1-5, 8-12, 16, 22 and 25 above, and further in view of US 6001336 to Gordon.

2. '151 fail to teach the instant wet milling or dry milling steps in the preparation of the suspension.

3. Gordon teaches preparing dry powders comprising hydrophobic and hydrophilic components comprise combining solutions or suspensions of components and spray drying to obtain uniform powders (abstract). In col. 5, Gordon teaches suspending hydrophobic drug in an aqueous solution of a hydrophilic excipient. Gordon teaches reducing the powders to the desired particle sizes can be carried out by any of the conventional methods including wet milling, pulverization etc (col. 3, L 60-67). Therefore, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention was made to employ any of the conventional techniques suggested

by Gordon in preparing the spray suspension o f'151 because Gordon suggests that such techniques have been employed to obtain uniform powder sizes. While Gordon suggests particle sizes of drug, '151 suggest powdered excipients and therefore a skilled artisan would have been able to employ wet milling to both active agent and excipient or either one of them depending on the particle sizes and their homogeneity.

4. Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4450151 as applied to claims 1-5, 8-12, 16, 22 and 25 above, and further in view of US 6841146 to Halswanter et al ('146).

5. '151 do not teach the claimed cellulose.

6. '146 teach sprayable compositions comprising a drug, microcrystalline cellulose and carboxyalkyl cellulose (abstract). '146 teaches that the compositions when sprayed generally are not retained well at the site of the application when sprayed with pump, particularly with aqueous based sprays (col. 1) and hence causes draining of the drug to be cleared from the site. In order to be able to spray and also retain. '146 suggests including microcrystalline cellulose in the spray compositions. '146 also refers to the prior art (col. 1-2) where cortisone is combined with microcrystalline cellulose. It would have been obvious for a skilled artisan to include microcrystalline cellulose in the spray composition of '151 because '146 suggests that the spray composition with microcrystalline cellulose is not too viscous so as to be able to spray and at the same time viscous enough to retain on the site such that the drug is retained at least temporarily. A skilled artisan would have expected to retain the composition of '151 on skin upon application.

Response to Arguments

7. Applicant's arguments filed 12-4-09 have been fully considered but they are not persuasive.

8. Applicants argue that '151 patent does not requires propellant as an essential component, and is required in the instant. However, admittedly '151 teaches propellant is needed to prevent clogging induced by the presence of a hydrophobic component. Therefore, irrespective of whether it is essential or non-essential, the prior art teaches the claimed propellant and therefore the rejection is proper.

9. It is argued that the composition of '151 is different from instant because the instant claims do not recite alcohol. However, instant comprising language allows fro the same. It is argued that the solid excipients need not be hydrophobic to be insoluble and may be hydrophilic. Applicants have not explained how the excipients of '151 (that are insoluble) are different from the instant insoluble excipient.

10. Applicants argue that the suspension o f'151 only refers to liquid phase with water and alcohol and not propellant, which is separate. However, the final composition of '151 still contains suspended solids that are insoluble and hence meet instant claims. It is not clear from the argument how the final composition of '151 is different from instant because instant claims do not recite separate or single phase.

11. While it is argued that '151 is silent about matrix, the burden is on applicants to show that the '151 does not form such a matrix. If a prima facie case of obviousness is established, the burden shifts to the applicant to come forward with evidence to rebut

the prima facie case. See, e.g., In re Dillon, 919 F.2d 688, 692, 16 USPQ2d 1897, 1901 (Fed. Cir. 1990).

12. It is argued that the particles of '151 are between 44-210 and not 38 microns or less. However, the rejection for particle sizes is made under 35 USC 103(a) and applicants failed to show any unexpected advantage of a difference of 6 microns (44-38=6). Similarly, it is argued that larger aggregates are formed by hydrophobic materials and instant example 2 shows that large particles must be preformed. It is argued that to avoid clogging the particles should be spherical, whereas '151 is silent regarding the shape. However, applicants have not compared the instant composition with that of the '151 to show why the '151 composition does not prevent clogging of the valve, when '151 also states the same. Further, applicants did not establish that '151 do not teach spherical particles nor a comparison with the closest art ('151) was made to establish that criticality of particle shape.

It is argued that Gordon does not remedy the short comings of '151 reference because very small particle drugs are taught by Gordon, whereas instant claims require larger aggregates. Thus, there is no suggestion in GORDON that in order to obtain larger, isodiametrical aggregate particles, one should use of the method described in claims 17 and 18. However, Gordon also teaches the same step of milling and further it is taught for uniform powder particles. Applicants arguement without any evidence that the milling of Gordon does not render spherical particles are not persuasive. Further the less than 5 microns size of instant claim 17 overlaps with less than 10 microns of

Gordon and hence the rejection is proper. Applicants did not show or explain why the microcrystalline cellulose of '146 (which also teaches carboxy alkyl cellulose) is not the same as instant claimed and hence would not result in the instant retention time and pumpability in the nasal cavity. The argument is only to carboxy alkyl cellulose even though microcrystalline cellulose was also taught.

Conclusion

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 9.00 AM -5.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila G. Landau can be reached on 571-272-0614. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lakshmi S Channavajjala/
Primary Examiner, Art Unit 1611
March 1, 2010